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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; The Stem Cell Therapeutic Outcomes Database, OMB No. 0915-0310 - Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443-9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database

Abstract: Given the rapid evolution of COVID-19 and its impact on those with compromised immune systems, it is imperative for the transplant community to continue collecting COVID-19 related data. Having access to COVID-19 vaccination status on blood stem cell recipients and understanding immune responses will assist with making informed decisions regarding direct clinical care. This will also inform critical policy decisions.
The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109–129, as amended, provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. It also maintains a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (e.g., bone marrow, cord blood, or other such product) from a donor.

Given the rapid evolution of the COVID-19 public health emergency and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations, HRSA wants to leverage the required data collection platform of the Stem Cell Therapeutic Outcomes Database to obtain vaccine information for all U.S. allogeneic hematopoietic stem cell transplant recipients.

Need and Proposed Use of the Information: To collect COVID-19 vaccine data, HRSA is requesting an extension of OMB's approval of both the Pre-Transplant Essential Data Form 2400 and Post-Transplant Essential Data (Post-TED) Form 2450. Collecting these data will help clinicians and policymakers to understand the landscape of vaccination among immunocompromised patients before and after a blood stem cell transplant.

HRSA will use this information to analyze outcomes based on vaccine manufacturer/type, doses received (including potential boosters), timing, and inform future vaccination strategies. Information currently collected regarding COVID-19 infections has already been used in research studies.

HRSA will use data collected prior to a patient receiving a blood stem cell transplant to

characterize frequencies of vaccination and level of protection afforded during and after transplant based on incidence of COVID infection. Post-transplant, this information can be used to assess vaccination rates and timing in blood stem cell recipients, characterize emerging vaccination strategies (which may include boosters), describe possible short and long-term side effects of vaccines, and analyze the incidence of COVID-19 infection based on different vaccination approaches. This information may guide future vaccination strategies or COVID treatments. Vaccination status of recipients may also be useful for risk adjustment in the annual transplant center specific analysis. For example, Centers for Disease Control and Prevention advisors could potentially use COVID-19 vaccination data on blood stem cell transplant recipients to make informed decisions regarding whether to issue any recommendations for this medically vulnerable population. The data collected under this extension request could help answer these and other questions.

The additional COVID-19 vaccine questions capture basic information on vaccination status, vaccine manufacturer/type, dose(s) given, and date(s) received. Patients who need a blood stem cell transplant are typically aware of their COVID-19 risk and vaccination status, and the information is also found on the vaccine cards carried by most recipients. Questions about vaccination status will likely become universal during the intake process at transplant centers for the next 12 months or more. For these reasons, HRSA believes the data will be readily available to data professionals working at transplant centers via the medical record. To reduce burden, an "unknown" option has been included for scenarios where the data cannot be located, and a "date estimated" checkbox has been included when the exact date of vaccination is not known. Although these questions are anticipated to be asked over the next 12 months and then removed, it is possible that other COVID-19 related questions may be requested for inclusion on these forms in the future given the rapid evolution of COVID-19 and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations.

Likely Respondents: Transplant Centers

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents[1]	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Baseline Pre-Transplant Essential Data (TED)	200	48	9,600	0.70[2]	6,720
Disease Classification	200	48	9,600	0.43[3]	4,160
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	45	9,000	1.00	9,000
100-day Post-TED	200	48	9,600	0.88	8,448
6 month Post-TED	200	43	8,600	0.85	7,310
1 year Post-TED	200	40	8,000	0.65	5,200
2 year Post-TED	200	34	6,800	0.65	4,420
3+ years Post-TED	200	172	34,400	0.52[4]	17,773
Total	**200**		**95,600**		**63,031**

1 The total of 200 is the number of centers completing the form; the same group will complete all of the forms.

2 The decimal is rounded down, and the actual number is .683333333.

3 The decimal is rounded down, and the actual number is .433333333.

4 The decimal is rounded up, and the actual number is .516667.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be

collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Executive Secretariat.

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